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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,088	12/11/2003	Gregory L. Sundberg	279.646US1	7977

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MINNEAPOLIS, MN 55402

EXAMINER

SMITH, TERRI L

ART UNIT	PAPER NUMBER
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3762

MAIL DATE	DELIVERY MODE
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06/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/734,088

Applicant(s)

SUNDBERG, GREGORY L.

Examiner

Terri L. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 21-42 is/are pending in the application.
- 4a) Of the above claim(s) 4,8-14,22 and 27-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7,21 and 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on 24 October 2006 with respect to claims 1–3, 5–7, 21 and 23–26 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.
2. Additionally, Applicant's arguments filed on 24 October 2006 have been fully considered but they are not persuasive. Examiner respectfully disagrees with Applicant's argument under the *Claims 2–3* heading regarding the compression limitations. Applicant has not specifically defined compression in the specification or in the claimed limitation set forth in the present invention. Applicant merely associates a structural feature with compression e.g., page 6, lines 5–6 and 10–12 in the specification. Consequently, it is the Examiner's position that any structure that reads on said limitation as disclosed in said sections of the Applicant's specification would satisfy said limitation.
3. Additionally, in response to Applicant's arguments that there is no suggestion to combine the references, the Examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. *In re NomiyaI*, 184 USPQ 607 (CCPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken, as a whole would suggest to one of ordinary skill in the art. *In re McLaughlin*, 170 USPQ 209 (CCPA). References are evaluated by what they suggest to one versed in the art, rather than by

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their specific disclosures. *In re Bozek*, 163 USPQ 545 (CCPA) 1969. In this case, the Examiner will once again combine several references to reject the claims set forth in the present invention.

Election/Restrictions

4. Newly submitted claims 37–42 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Inventions of Group II (combination), claims 37–42 and Group I (subcombination), claims 1–3, 5–7, 21 and 23–26 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination (Group II) as claimed does not require the particulars of the subcombination (Group I) as claimed because Group II does not require one or more recesses and at least one conductor disposed outside the one or more recesses. The subcombination has separate utility such as not requiring a coiled conductor positioned within a C-shape and at least one cable conductor disposed distally between the first and second ends; but rather bare wires disposed within the insulation of the lead body.

Since Applicant has received an Action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 37–42 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter which was not described in the original specification is one or more fillers “longitudinally extend from” and at least a first and second insulated cable conductor are disposed “distally” in combination with the other elements in the claim(s). When teaching the longitudinal characteristic, the original specification generally refers to a longitudinal axis as it relates to a coil conductor and being offset from a lead body (e.g., page 2, lines 7, 8, 16; page 5, lines 18 –20; page 7, lines 7–8); the specification does not disclose anything about one or more fillers longitudinally extend from a first end to a second end. Additionally, the only mention of the distal characteristic appears on page 3 in the next to last line, which is describing the lead body, not at least a first and as second insulated cable conductor are disposed distally between the first and second ends as set forth in the claimed invention of the present invention.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the Applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the Applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1–3, 5–7 and 23–24 are rejected under 35 U.S.C. 102(e) as being anticipated by Gardeski et al., U.S. Patent 7,130,700.

9. Gardeski et al. disclose a tubular body, at least one electrode, at least one conductor (e.g., TITLE; FIGS. 2 and 7; FIG. 8; column 4, lines 19–20; column 15, lines 13–15); one filler include one or more generally C-shaped recesses (e.g., FIG. 8, element 134, being interpreted as a filler, and 119 and 121, being interpreted as one or more generally C-shaped recesses) adjacent an insulated conductor (e.g., element 150); and one conductor is disposed outside one recess (e.g., 150 is disposed outside of recess 119); a coiled conductor forming a lumen (claim 5) (e.g., elements 156 and 157); one or more fillers is formed of silicone (claim 7) (e.g., column 14, lines 54–56).

10. Claims 1–3, 5–7 and 23–25 are rejected under 35 U.S.C. 102(e) as being anticipated by Cross, Jr. et al., U.S. Patent 5,935,159.

11. Regarding claims 1–3, 6 and 23, Cross, Jr. et al. disclose a tubular body, at least one electrode, at least one conductor (e.g., FIGS. 1, 7 and 12; elements 216 and 218, and 404 and 406 insulation);

one filler includes one or more generally C-shaped recesses (e.g., elements 202 and 402, being interpreted as a filler, and the inner surface of the lumens housing elements 216 and 218, and 404 and 406, being interpreted as one or more generally C-shaped recesses);

and one conductor is disposed outside one recess (e.g., 418, coil conductor is disposed outside of the inner surface of the lumen housing element 406).

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12. With respect to claims 5, 7, 24 and 25, Cross, Jr. et al. disclose a coiled conductor forming a lumen (claim 5) (e.g., elements 418 and 420); one or more fillers is formed of silicone (claim 7) (e.g., column 3, lines 13–15); an active fixation assembly (claim 24) (e.g., column 5, line 11); insulation include at least one of PTFE or polyurethane (claim 25) (column 3, lines 25–26).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gardeski et al., U.S. Patent 7,130,700.

15. Gardeski et al. disclose bending flexibility may be uniquely tailored to specific applications through careful selection of inner and outer insulating member materials (e.g., column 7, lines 13–15, wherein the inner insulating member having been cited as the one or more fillers herein above), but not explicitly a flexibility of one or more fillers is greater than a flexibility of a tubular body. It would have been an obvious matter of engineering design choice to one of ordinary skill in the art at the time the invention was made to modify the inner insulating member as taught by Gardeski et al., to have a flexibility greater than a flexibility of a tubular body, because Applicant has not disclosed that a flexibility of one or more fillers is greater than a flexibility of a tubular body provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have

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expected the Applicant's invention to perform equally well with the flexibility of the inner insulating member as taught by Gardeski et al., because the material of the inner insulating member in combination with the outer insulating material is made out of the same material used by the Applicant and it is carefully chosen to enhance the flexibility of the lead to provide optimum lead handling and manipulation during implant.

Therefore, it would have been an obvious matter of engineering design choice to modify the inner insulating material to obtain the invention as specified in the claim.

16. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cross, Jr., et al., U.S. Patent 5,935,159 as applied to claim 1 above, and in view of Gardeski et al., U.S. Patent 7,130,700.

17. Cross, Jr. et al. disclose an outer surface portion of at least one conductor contacting an outer surface portion of another conductor (FIG. 7, elements 216 and 218), but not that one is a coiled conductor and one is a cable conductor. However, Gardeski et al. disclose that one is a coiled conductor and one is a cable conductor (e.g., column 15, lines 15-18) to provide an efficient, diverse, optimum and reliable lead for effective administration of therapy. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Cross, Jr. et al. to include a coiled conductor and a cable conductor, as taught by Gardeski et al. to provide an efficient, diverse, optimum and reliable lead for effective administration of therapy.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

19. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is (571) 272-7146. The Examiner can normally be reached on 7:30 a.m. - 4:30 p.m..

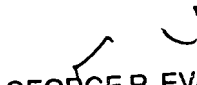
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


TLS
May 24, 2007

24 May 2007


GEORGE R. EVANISKO
PRIMARY EXAMINER

5/26/7